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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

CHUI, MEI PING

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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11/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,134	Applicant(s) ANDERSCH ET AL.	
	Examiner MEI-PING CHUI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/22/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

Receipt of Amendments/Remarks filed on 06/22/2009 is acknowledged. Claims 2, 13-14 are pending in the application. Claims 1, 3-12 have been cancelled; claim 2, 13 have been amended; new claim 14 is added.

Receipt of Information Disclosure Statement filed on 06/22/2009 is acknowledged. It has been considered and placed in the file.

Upon further consideration, Applicants' amendments necessitated the new grounds of rejection presented in this Office Action. Accordingly, this action is made FINAL.

Status of Claims

Accordingly, claims **2, 13-14** are presented for examination on the merits for patentability.

Rejection(s) not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

New Ground of Rejection

Claim Rejection - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement of the Invention

Claims 2, 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 2, 13-14 while being enabling for a composition comprises a mixture of active compounds: thiodicarb and imidacloprid, the mixture does not reasonably provide enablement for synergistic activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

An analysis of whether the scope of a particular claim(s) is actually supported by the disclosure in a patent application requires a determination of whether the disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim at issue so as to enable one skilled in the pertained art to use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ 2d 140 (Fed. Cir. 1988). Therefore, the test of enablement is not whether experimentation is necessary, but rather, if experimentation is in fact necessary, whether it is reasonably considered to be undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). Determining the issue of enablement with respect to a claim is a question of law based on underlying factual findings. *In re Vaeck*, 20 USPQ 2d, 1444 (Fed. Cir. 1991). More particularly, there are many factors to

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be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and whether any necessary experimentation is reasonably considered to be “undue”. See *In re Wands* at page 1404. MPEP § 2164.01(a). The court in *In re Wands* set forth the following factors to be considered, which included, without limitation, the: 1). scope or breadth of the claims; 2). nature of the invention; 3). relative level of skill possessed by one of ordinary skill in the art; 4). state of, or the amount of knowledge in, the prior art; 5). level or degree of predictability, or a lack thereof, in the art; 6). amount of guidance or direction provided by the inventor; 7). presence or absence of working examples; and 8). quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner’s position that one skilled in the art could not practice the invention without undue experimentation.

Nature of the Invention:

The nature of the invention is a composition comprises a mixture of thiodicarb and imidacloprid, when presents in weight ratio ranging between 100:1 and 1:50 would produce synergistic activity for controlling animal pests.

Scope or breadth of the claims:

The claims are broader in scope than the enabling disclosure. The instant specification provides only one testing data of the claimed mixture (thiodicarb and imidacloprid at page 36) in a weight ratio of 25:1, but Applicant is purporting to claim

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the composition would produce synergistic effect for controlling animal pests when they are present in a wide range of weight ratio between 100:1 and 1:50.

Amount of guidance or direction provided by the inventor:

The instant specification (Table B, page 36) provides the result of *Phaedon cochleariae* Larvac Test for the claimed mixture (thiodicarb and imidacloprid), in which it shows when thiodicarb (concentration of 100 p.p.m.) and imidacloprid (concentration of 4 p.p.m.) acts alone, each resulted in 45 % of kill rate; and when thiodicarb and imidacloprid is combined (25:1), its combined killing effect was 80 %. However, the combined killing effect as disclosed, in fact, provides the evidence of an additive killing effect (based on the sum of 45 % killing rate from each compound set forth above) rather than a synergistic killing effect (see Specification: page 36):

Active:	Concentration (p.p.m.)	Calc. kill rate (%)	Det. kill rate (%)
Thiodicarb	100	45	-
Imidacloprid	4	45	-
Mixture: thiodicarb + imidacloprid	100 + 4 (25:1)	69.75	80 .

In addition, the specification only performs the testing on *Phaedon cochleariae* (mustard leaf beetle), but is silent whether the claimed mixture is effective for controlling other types of animal pests or not.

Presence or absence of working examples, and level or degree of predictability in the art:

The specification only provides a single testing data (weight ratio of 25:1) for the claimed mixture (thiodicarb and imidacloprid), but does not provide any additional result for other weight ratio that falls within the synergistic ranges of 100: 1 to 1:50, as claimed.

It is well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicant invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claim(s) which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of unexpected synergistic effects observed from the claimed thiodicarb and imidacloprid mixture between the weight ratio 100:1 to 1:50; the working embodiments regarding the composition, for controlling animal pests, comprises a synergistically effective mixture of thiodicarb and imidacloprid in weight ratio between 100:1 and 1:50, is therefore not enabled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treacy et al. (EP 1198170 B1) in view of Uhr et al. (U. S. Patent No. 6,828,275).

Applicants Claim

Applicants claim a composition comprising a synergistically effective mixture of thiodicarb and imidacloprid, and optionally extenders and/or surfactants, wherein the weight ratio of the thiodicarb to imidacloprid is between 100:1 and 1:50. Applicants also claim a method of controlling animal pests by applying said composition to an area be rid of said pests.

Determination of the scope and content of the prior art (MPEP 2141.01)

Treacy et al. teach an insecticidal composition comprising a neuronal sodium channel antagonist and one or more second active compounds selected from the group, i.e. carbamates and acetylcholine receptor ligands in synergistically active amounts; wherein the carbamate can be thiodicarb and the acetylcholine receptor ligand compound

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can be imidacloprid, and optionally with other customary formulation adjuvants (page 2: [0004]; page 4: [0017], [0021], line 5).

Treacy et al. also teach that the insecticidal composition has superior insecticidal property and is especially useful for the control of agro-horticultural pests. The composition can be applied to the plant and plant parts, or to the insect habitat, or to the locus of hygienic pest, in which the ratio of the active insecticides set forth above is about 1 part of the neuronal sodium channel antagonist to about 0.01-100 parts of the one or more second active compounds (e.g. thiodicarb and imidacloprid) by weight. Such combination is highly effective for the protection of growing and harvested plants from ravages of insects (page 4: [0023-0025]).

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

- (1) Treacy et al. do not exemplify the amount of thiodicarb and imidacloprid, as claimed.
- (2) Treacy et al. also do not explicitly teach the composition comprising extenders and/or surfactants, as claimed. However, this deficiency is cured by Uhr et al.

Uhr et al. teach a method for the protection of wood against insecticidal attack comprising the step of applying a synergistically effective of a mixture of insecticides, i.e. fipronil, thiodicarb and/or imidacloprid (column 10, lines 3-4, 38, 40). Uhr et al. also teach that the insecticidal combination can provide synergistic insecticidal activity against wood-destroying and wood-discoloring fungi, as well as additional synergistic effects or synergisms against attack by insects (column 9, line 64 to column 10, line 2).

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Uhr et al. further teach that when preparing the formulation, additional ingredients, i.e. extenders, surfactants like emulsifiers, can be included (column 15, lines 59-65).

***Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)***

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teachings of Treacy et al. with Uhr et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to choose the desirable insecticide combination, i.e. thiodicarb and imidacloprid, and then adjusts the appropriate ratio of their amounts to its desirable level for controlling animal pests, depending on the type of pest one wishes to attain, as suggested by Treacy et al.

One of ordinary skill also would have been motivated to further incorporate optional ingredients, i.e. extenders or surfactants, into the composition, dependent on the formulations one wishes to attain, as suggested by Uhr et al.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. The invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Applicants' amendments necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR.

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Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. C./

Examiner, Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616